REMARKS

I. Status of the Claims

Claims 15, 16 and 18-22 have been canceled. Claims 30-34 are now pending. Claims 30-34 have been amended to recite that the skin care composition comprises:

(I) a non-denatured soy product derived from soybean selected from (a) a liquid soy product present in the composition at from about 50 to about 99% by weight or (b) a solid soy product present in the composition at from about 1 to about 50% by weight, wherein said non-denatured soy product contains trypsin inhibitory activity and the ingredients naturally found in soybeans, at the relative concentrations as found in soybeans; and

(II) a stabilizing system comprising a member selected from the group consisting of (i) from about 0.001 to about 20% by weight of an antioxidant; (ii) from about 0.001 to about 20% of a chelating agent; or (iii) from about 0.01 to about 20% of a preservative.

Support can be found in the Specification at least at page 7, lines 3-5; page 8, lines 6-10; page 9, lines 14-16 and page 10, lines 6-8 and lines 13-16. Claims 30-34 have also been amended so to replace "nondenatured" with "non-denatured" so that the claim language is consistent. Accordingly, no new matter has been introduced by this Amendment.

II. Claim Rejections – 35 U.S.C. § 102

The Examiner has rejected claim 34 under 35 U.S.C. 102(a) as allegedly being anticipated by WO 99/36050 ("Kelly et al."). Applicants respectfully traverse this rejection for the following reasons.

Claim 34 relates to a method of treating and preventing sunburn on the skin of a mammal comprising the step of applying a skin care composition comprising a non-denatured soy product containing trypsin inhibitory activity and a stabilizing system. As discussed in the Specification, a "non-denatured soy product" is "…a soy product in which the processing for the derivation of such soy product (e.g., the temperature, extraction media) did not eliminate its protease inhibitory activity." Indeed, the non-denatured state of the soy product of this invention is measured by the presence of an intact soybean trypsin inhibitor (STI) protein. [Specification page 7, lines 10-14.] The skin care composition used in the method of claim 34 comprises:

(I) a non-denatured soy product derived from soybean selected from (a) a liquid soy product present in the composition at from about 50 to about 99% by weight or (b) a solid soy product present in the composition at from about 1 to about 50% by weight, wherein said non-denatured soy product contains trypsin inhibitory activity and the ingredients naturally found in soybeans, at the relative concentrations as found in soybeans; and

(II) a stabilizing system comprising a member selected from the group consisting of (i) from about 0.001 to about 20% by weight of an antioxidant; (ii) from about 0.001 to about 20% of a chelating agent; or (iii) from about 0.01 to about 20% of a preservative.

Kelly et al. relates to a method for protecting skin from either UV-induced immunosuppression or from UV-induced skin damage comprising the topical administration of a composition containing an extract of soy or clover and/or isoflavone compounds. According to Kelly et al.,

> Extracts of soy or clover may be prepared according to WO93/23069, the teachings of which are incorporated by reference. As described in WO93/23069 soy or clover may be extracted with a mixture of organic solvent (such as ethanol, chloroform, acetone, ethyl acetate and the like) and water. The ratio of solvent in water may be from 0.1% to 99.9%, preferably 40% to 60%. [Kelly et al., p. 11, lns. 22-27].

The Examiner argues that "No where in the extraction methods do both references state the use of enzymes, elevated temperature, or acids, which are well-known methods of denaturing proteins." [Office Action, p. 3]. Applicants note that Kelly et al. uses a preferred ratio of 40% to 60% of solvent in water. As demonstrated by the Declaration of Yaping Hu filed January 10, 2011, soybeans extracted with 60% ethanol did not have trypsin inhibition activity. Clearly, as the preferred extracts of Kelly et al. would be denatured and free from trypsin inhibitory activity, Kelly et al. fails to recognize the benefits of a soy extract containing trypsin inhibitory activity. In answer to this argument, the Examiner argues that Kelly et al. is not limited to 40-60% solvent ratio and that the lower limit of 0.1% solvent broadly disclosed would not denature the soy extract. In response, Applicants submitted the Declaration of Miri Seiberg filed December 4, 2009 ("2009 Seiberg Declaration"). The 2009 Seiberg Declaration demonstrates that a ratio of organic solvent in water as low as 0.1% would not effectively facilitate the intent and purpose of the Kelly et al. compositions. Indeed, a much higher organic solvent content is necessary to extract isoflavones from soy.

However, the Examiner now argues, "the ratio of organic solvent to water in Kelly et al. is not limited to 0.1% but covers a much broader range. It is this range taught by Kelly et al. that encompasses the example of ethanol/water found in Applicant's specification." [Office Action, p. 4, 1st ¶].

Applicants note, however, when the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, in order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." See, e.g., *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 °C did **not** describe the claimed range of 330-450°C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350°C) and the claimed range, that overlap was not sufficient for anticipation. "[T]he disclosure of a range is no more a disclosure of the end points of the range than it is each of the intermediate points." *Id.* at 1000, 78 USPQ2d at 1424.

The Examiner also argues that the "recitation of 'non-denatured' soy product is inherent in the reference because soy beans are extracted without using enzymes and/or temperature." [Office Action, p. 2]. Applicants respectfully disagree. According to Kelly et al.,

> Raw plant material may be dried, chaffed or otherwise comminuted and then subject to extraction. The resultant organic solvent layer following extraction is removed such as by distillation, and the aqueous layer and residual material from the organic layer concentrated as desired, such as distillation. In respect of soy, beans may be treated to remove the hull (such as by using a tumble mill which splits the beans into two cotyledons and a hypocotyls which may be separated from another). Cotyledons, and optionally hypocotyls, may be comminuted and then subject to extraction as described above [Kelly et al., p. 12, lns. 1-7].

Accordingly, Kelly et al. does use heat in the extraction process. In fact, the heat necessary for the distillation process would most definitely denature the soy product. Accordingly, even if one of ordinary skill in the art were somehow motivated to use a solvent ratio far outside of the preferred ratio 40% to 60% of solvent in water, the distillation step

would denature the soy product. Accordingly, Kelly et al. simply fails to anticipate a non-denatured soy product containing trypsin inhibitory activity.

Further, as amended, the claims recite that the non-denatured soy product contains the ingredients naturally found in soybeans, at the relative concentrations as found in soybeans. In contrast, Kelly et al. specifically teach that the soy beans are treated to remove the hull "such as by using a tumble mill which splits the beans into two cotyledons and a hypocotyls which may be separated from one another." [Kelly et al., p. 12, lns. 3-6]. As discussed above, Kelly et al. states that the plant extracts are prepared according to WO '069. WO '069 teaches that the hull and hypocotyls "represent only a small proportion by weight (8% and 2% respectively) of the intact bean. [WO '069 p. 12, ¶3]. Therefore, Kelly et al. fails to teach or suggest a non-denatured soy product containing the ingredients naturally found in the whole soybeans.

Additionally, there is absolutely no teaching or suggestion in Kelly et al. of a non-denatured soy product selected from (a) a liquid soy product present in the composition at from about 50 to about 99% by weight or (b) a solid soy product present in the composition at from about 1 to about 50% by weight. In fact, Kelly et al. does not even mention whether the soy products briefly described are in liquid or solid form. Kelly et al. also fails to teach or suggest a stabilizing system comprising a member selected from the group consisting of (i) from about 0.001 to about 20% by weight of an antioxidant; (ii) from about 0.001 to about 20% of a chelating agent; or (iii) from about 0.01 to about 20% of a preservative.

For these reasons, Kelly et al. fails to disclose the claimed invention with sufficient specificity to constitute anticipation and the rejection should be withdrawn. Further, Kelly et al. fails to render the presently claimed invention obvious as there is simply no teaching or suggestion of a skin care composition comprising:

(I) a non-denatured soy product selected from (a) a liquid soy product present in the composition at from about 50 to about 99% by weight or (b) a solid soy product present in the composition at from about 1 to about 50% by weight, wherein said non-denatured soy product contains trypsin inhibitory activity and the ingredients naturally found in soybeans, at the relative concentrations as found in soybeans; and

(II) a stabilizing system comprising a member selected from the group consisting of (i) from about 0.001 to about 20% by weight of an antioxidant; (ii) from about 0.001 to about

20% of a chelating agent; or (iii) from about 0.01 to about 20% of a preservative. Accordingly, Applicants respectfully request withdrawal of this rejection.

III. Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected claims 30-33 under 35 U.S.C. 103(a) as allegedly being obvious over JP 5-320061, translation of record ("Tokuyama") in view of JP 62-36304, of record ("Mizue"). Applicants respectfully traverse this rejection for the following reasons.

The inventions of claims 30-33 relate to non-denatured soy product containing compositions useful for the care of the skin, such as, evening skin tone, treating acne, evening the texture of the skin, increasing the elasticity and firmness of the skin, reducing the shine and oiliness of the skin and treating cellulite in the skin. The composition used in the claimed methods comprises:

(I) a non-denatured soy product selected from (a) a liquid soy product present in the composition at from about 50 to about 99% by weight or (b) a solid soy product present in the composition at from about 1 to about 50% by weight, wherein said non-denatured soy product contains trypsin inhibitory activity and the ingredients naturally found in soybeans, at the relative concentrations as found in soybeans; and

(II) a stabilizing system, said stabilizing system comprising a member selected from the group consisting of (i) from about 0.001 to about 20% by weight of an antioxidant; (ii) from about 0.001 to about 20% of a chelating agent; or (iii) from about 0.01 to about 20% of a preservative.

Tokuyama relates to an oxygen elimination agent, using legumes as the raw material that acts as an anti-oxidant and is safe and inexpensive and that can be used in broad range of fields such as medicinal drugs, food products and cosmetic products. Tokuyama exemplifies three types of legume extracts: Example 1: extracts of legumes obtained through the use of enzymes and boiling; Example 2: organic extractions of legumes using 90% alcohol; and Example 3: the use of a pressing machine and then separating juice from residue.

The Examiner argues that in Examples 2 and 3, the soy extracts were not heated. However, Example 2 uses 90% alcohol for the extraction of legumes. As shown by the Declaration of Yaping Hu, soybeans extracted with 60% ethanol did not have trypsin

inhibition activity. Accordingly, the extraction described in Example 2 with an even higher percentage of solvent (90%) would clearly cause a greater loss of trypsin inhibitory activity.

With respect to Example 3, Tokuyama fails to describe whether the juice or the residue obtained is useful. Applicants presume it is the juice (and not the residue) which only constitutes 0.6 liters of the 3 kg of green soybean or about only 20% of the starting material. Further, it is unclear whether the product of Example 3 is considered to be an example of the claimed invention. When describing the figures, Tokuyama does not indicate which "product of this invention" was used. It could be Example 1, 2 or 3 or another legume extract. In any case, Example 3 which obtained only 0.6 liters of juice clearly does not relate to a soy product containing "ingredients naturally found in soybeans, at the relative concentrations as found in soybeans." Accordingly, Tokuyama fails to render obvious the claimed non-denatured soy product which contains both trypsin inhibitory activity and the ingredients naturally found in soybeans at the relative concentrations as found in soybeans.

The Examiner argues that the "specification clearly defines 'denaturation' as a loss of enzyme activity" citing page 7, first paragraph of the Specification. According to the Examiner because Tokuyama recites that black soybeans possess tyrosinase inhibitory activity in Table 1, the soy beans recited in Tokuyama are not denatured and inherently possess STI's protease inhibitory activity. [Office Action, p. 9, 3rd ¶]. Applicants respectfully disagree.

In the first paragraph of page 7 of the Specification, Applicants define denaturation:

> "Denaturation" is defined in the Bantam Medical Dictionary (1990 edition) as "the change in the physical and the physiological properties of a protein, that are brought about by heat, X-rays or chemicals. These changes include loss of activity (in the case of enzymes) and loss (or alteration) of antigenicity (in the case of antigens)". What is meant by "non-denatured soy product" is a soy product in which the processing for the derivation of such soy product (e.g., the temperature, extraction media) did not eliminate its protease inhibitory activity." [Specification, p. 7, ¶ 1].

Accordingly, the Specification clearly states that non-denatured soy product is a soy product in which the processing for the derivation of such a soy product did not eliminate its protease inhibitory activity. Contrary to the Examiner's position, the Specification does not define denaturation as a loss of enzyme activity. Further, tyrosinase inhibitory activity and trypsin inhibitory activity are not the same. "Inhibitory activity" relates to the activity of the

agent(s) that causes the inhibition, which could be a small molecule, a protein, or any other entity. All soy extracts, denatured and non-denatured, contain isoflavones (small molecules which are known as tyrosinase inhibitors), and therefore all soy extracts inhibit tyrosinase. However, only non-denatured soy extracts contain additional active molecules which exhibit trypsin inhibitory activity. As set forth in the Declaration of Miri Seiberg filed January 10, 2011 and appended publications, isoflavones, not being proteins, cannot undergo denaturation. Further, the Declaration of Yaping Hu demonstrates that soy preparations prepared according to the present invention exhibit trypsin inhibition activity. In contrast, as also demonstrated by the Declaration of Yaping Hu, genestein and daidzin, two major soy isoflavones do not have trypsin inhibition activity.

Accordingly, for all these reasons, Applicants maintain that Tokuyama does not teach or suggest a non-denatured soy product containing trypsin inhibitory activity and the ingredients naturally found in soybeans, at the relative concentrations as found in soybeans.

The Examiner also relies upon Mizue as teaching stabilizing soy extracts in cosmetic compositions with preservatives. However, Mizue fails to remedy the fatal deficiency of Tokuyama. Adding preservatives to a composition that does not contain soy trypsin inhibitory activity will not resurrect the activity of the proteins which originally had such trypsin inhibitory activity.

Further, there is absolutely no teaching or suggestion in either reference of a non-denatured soy product selected from (a) a liquid soy product present in the composition at from about 50 to about 99% by weight or (b) a solid soy product present in the composition at from about 1 to about 50% by weight or the stabilizing system comprising a member selected from the group consisting of (i) from about 0.001 to about 20% by weight of an antioxidant; (ii) from about 0.001 to about 20% of a chelating agent; or (iii) from about 0.01 to about 20% of a preservative.

For the reasons discussed above, Tokuyama and Mizue, taken alone or in combination, fail to teach or suggest the use of non-denatured soy products containing trypsin inhibitory activity in skin care compositions for evening skin tone, treating acne, evening the texture of the skin, increasing the elasticity and firmness of the skin, reducing the shine and oiliness of the skin and treating cellulite in the skin. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness and the rejection should be withdrawn.

IV. Conclusion

For the reasons set forth above, Applicants respectfully request withdrawal of all outstanding rejections. If the Examiner feels that a discussion with Applicants' representative would be helpful in resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP0518/ALC. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 10-0750/JBP0518/ALC.

Respectfully submitted,

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